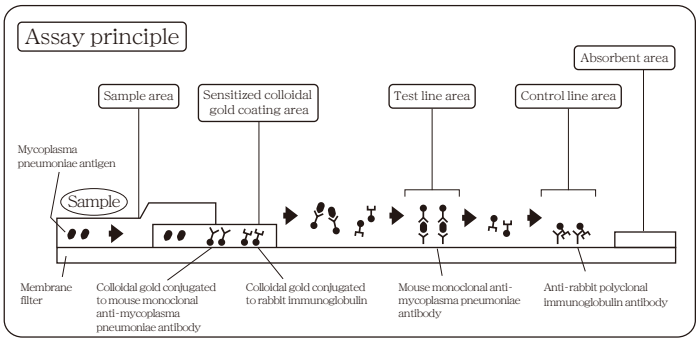
Read this Instructions For Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Mycoplasma pneumoniae antigen kit

Quick Chaser® Myco



[General precautions]

1) For in vitro diagnostic use only.
2) The diagnosis of mycoplasma pneumoniae infection should be comprehensively made not only by test result of this product, but also in conjunction with the assessment of clinical progress and results of other tests.
3) Procedures which are not described in instructions for use, are not guaranteed.

[Contents]

1) Test plate - 10 tests
   - Mouse monoclonal anti-mycoplasma pneumoniae antibody
   - Colloidal gold conjugated to mouse monoclonal anti-mycoplasma pneumoniae antibody
2) Extraction reagent solution vial - 10 vials
   Extraction reagent solution is buffer containing detergent.
3) Swab (for pharyngeal swab specimen) - 10 pieces
4) Rack (for Extraction reagent solution vial) - 1 piece
5) Filter (for Extraction reagent solution vial) - 10 pieces
6) Blue cap (for temporary storage of Extraction reagent solution vial) - 10 pieces
7) Name label - 1 sheet

[Intended Use]

For detection of mycoplasma pneumoniae antigen in pharynges
(An aid of diagnosis for an infection of mycoplasma pneumoniae)

[Principle of the test]

Quick Chaser® Myco is the in- vitro reagent for detection of mycoplasma pneumoniae antigen based on Immunochromatographic Assay.

Colloidal gold conjugated to mouse monoclonal anti-mycoplasma pneumoniae antibody and colloidal gold conjugated to rabbit immunoglobulin for control line are coated in sensitized colloidal gold coating area in test plate. And mouse monoclonal anti- mycoplasma pneumoniae antibody is immobilized in test line area and anti- rabbit immunoglobulin antibody for control line is immobilized in control line area.

According to immunochromatographic principle, when sample is added to the sample area, in the presence of mycoplasma pneumonia antigen, it migrates to the area between sample area and test line area, where respectively reacting with colloidal gold conjugated to mouse monoclonal anti-mycoplasma pneumoniae antibody and moreover, reacts with mouse monoclonal anti-mycoplasma pneumonia antibody and it is caught in test line area.

As the result, purple- red line is visible. Moreover, purple-red line is also simultaneously visible for catching colloidal gold conjugated to rabbit immunoglobulin by anti-rabbit immunoglobulin antibody in control line area, regardless of presence of mycoplasma pneumoniae antigen.

[Procedural precautions]

1) Do not use saliva and sputum as a specimen.
2) Collected specimen should be prepared as sample in accordance with after-mentioned "**Preparation of sample in Test procedure**" and tested as soon as possible.
3) Add fixed volume (3 drops) to the center of sample area from tip of filter about 10mm away from the sample area so as to make droplets. In case of adding other than fixed volume, an accurate reaction may not be performed.
4) Bring test plate and extraction reagent solution to 15 ～30 ℃ prior to testing.
5) Keep interpretation time inevitably because it causes false-negative and false-positive.
6) Interfering substances and medications
   The following substances and blood did not interfere the performance of this product at the concentration listed below:

Acetyl salicylate (5 mg/mL)	
Diphenhydramine hydrochloride (0.63mg/mL)	
Dextromethorphan hydrogen bromide (0.63 mg/mL)	
Cold medicine ①	Acetaminophen concentration (5 mg/mL)
Cold medicine ②	Ibuprofen concentration (2.5 mg/mL)
Nasal drop ①	containing Sodium cromoglicate, Chlorpheniramine monomaleate, Naphozoline hydrochloride (10%)
Nasal drop ②	containing Ketotifen fumarate (10%)
Gargle ①	containing Tincture of Myrrh (1 %)
Gargle ②	containing Povidoneiodine (3 %)
Intraoral antiphlogistics	containing Sodium Azulene Sulfonate (10 %)
Throat candy ①	containing Di-potassium Glycyrrhizinate (20 mg/mL)
Throat candy ②	containing Nandina Fruit Extract (Dry) (10 mg/ml)
Throat candy ③	containing Cetylpyridinium chloride (20 mg/mL)
Blood (1%)	

7) Cross reactivity
   Cross reactivity with the following virus and bacteria were not observed.

・Othermycoplasmagenus

Mycoplasma fermentans	*Mycoplasma genitarium*
Mycoplasma orale	*Mycoplasma salivarium*
Mycoplasma buccale	*Mycoplasma hominis*
Mycoplasma faucium	*Mycoplasma penetrans*
Mycoplasma laidlawii	*Ureaplasma urealyticum*

・Bacteria

Candida albicans	*Chlamydophila pneumoniae*
Chlamydia trachomatis	*Citrobacter freundii*
Enterobacter aerogenes	*Enterobacter cloacae*
Escherichia coli	*Haemophilus influenzae*
Klebsiella pneumoniae	*Listeria monocytogenes*
Legionella pneumophila	*Moraxella catarrhalis*
Proteus mirabilis	*Pseudomonas aeruginosa*
Serratia marcescens	*Staphylococcus aureus*
Staphylococcus epidermidis	*Streptococcus anginosus*
Streptococcus mutans	*Streptococcus pneumoniae*
Streptococcus pyogenes (group A)	*Streptococcus agalactiae (group B)*
Streptococcus(group C)	

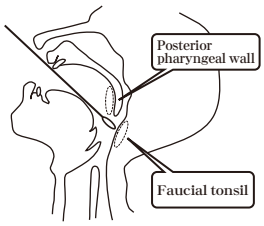
・Virus

Influenzavirus A	Influenzavirus B
Adenovirus Type 1	Adenovirus Type 2
Adenovir-us Type 3	Adenovirus Type 4
Adenovirus Type 5	Adenovirus Type 7
Human Coronavirus	Coxsackie virus A9
Coxsackie virus B5	Human Echovirus 9
Herpes simplexvirus Type1	Human Metapneumovirus
Mumps virus	Parainfluenza virus 1
Rhinovirus 8	Respiratory Syncytial virus A
Respiratory Syncytial virus B	

[Test procedure]

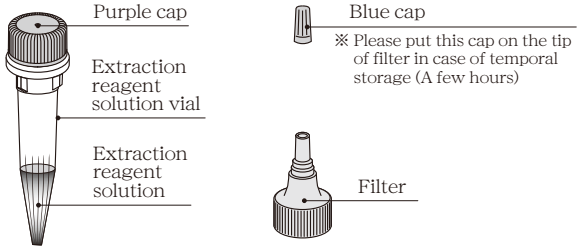
●Specimen collection

1) Preparation of specimen collection
   ① Swab: Use swab, included in this test kit.
   ② Extraction reagent solution: Use it without preparation.
2) Specimen collection
   ・Pharyngeal swab specimen
   Insert swab from oral cavity into pharynx slowly and collect mucous membrane epidermis by rubbing posterior pharyngeal wall or faucial tonsil several times.



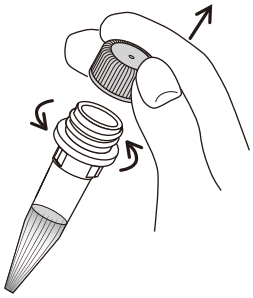
   Note) Mycoplasma pneumoniae multiply with lower respiratory tract. Antigen of enough quantity cannot be collected with upper respiratory tract. Collect specimen by letting the spherical tip touch the part near posterior pharyngeal wall surely so as to rub a part near lower respiratory tract. In addition, do not use nasopharyngeal swab because an insufficient collection of specimen is thought about.

●Detail of Extraction reagent solution vial

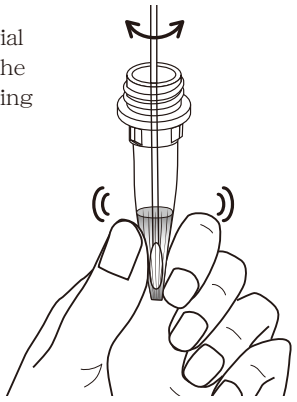


●Preparation of sample

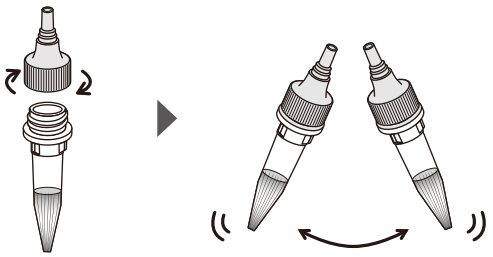
① Loosen purple cap with turning it counterclockwise.



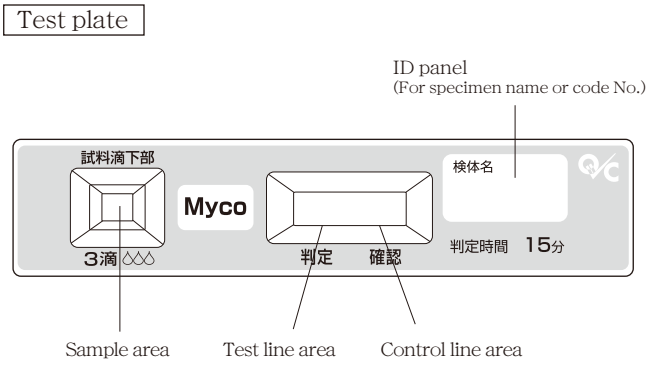
② Insert the spherical tip with specimen into the bottom of extraction reagent solution vial and press spherical tip from the outside of the vial for extracting specimen. Turn the swab clockwise and counterclockwise about five times and rub the spherical tip on the inside wall and bottom of the vial. Take swab out of the vial with squeezing out liquid from the spherical tip, pressing spherical tip.



③ Install filter and gently shake the vial several times to mix specimen thoroughly. The sample is ready for use.

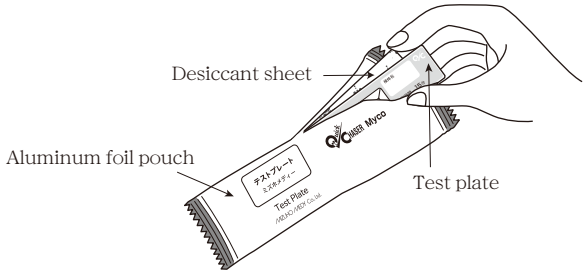


●Details of test plate



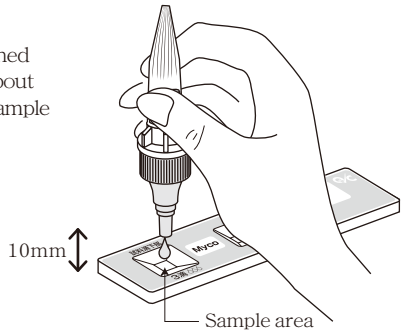
●Test procedure

1) Preparation of reagent
   Test plate: No prior preparation required.
2) Test procedure
   ① Remove test plate from aluminum foil pouch. Discard desiccant sheet included in aluminum foil pouch.

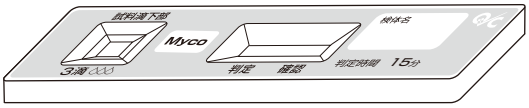


② Add 3 drops (About 100 μL) of sample vertically to sample area of test plate from extraction reagent solution vial including prepared sample with avoiding contact of tip of extraction filter with sample area.

※Add the predetermined amount of sample about 10 mm away from sample area of test plate.



③ Leave to react at 15～30° C.
Visually interpret test result by lines in test line area and control line in control line area after 5 ～15 minutes.



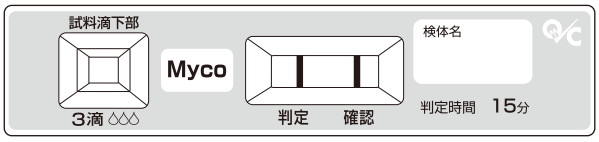
[Interpretation]

Interpret by existence of red-purple lines in test line area and control line area.

《Positive》

Both test line and control line appear.

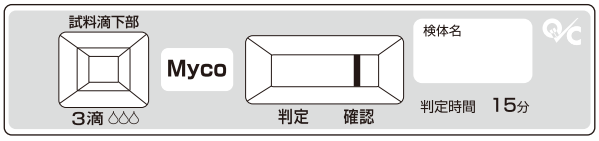
Positive



《Negative》

Only control line appears.

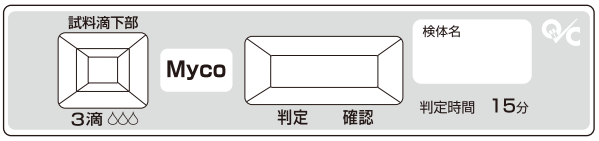
Negative



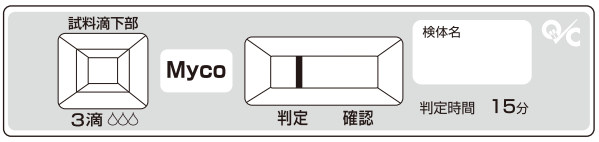
《Retest》

If both test lines and control line do not appear or no control line appear, operational mistakes such as the lack of sample amount are thought about. Recheck test procedure and retest with new test plate. If the same result comes out in the retest again, confirm it with other method.

Retest



Retest



●**Interpretational precautions**

1) In case test line and control line appear at 5～15 minutes after adding sample, it can be interpreted as positive. Negative should be interpreted at 15 minutes after adding sample. Streak line might appear before 15 minutes temporarily. Do not interpret the temporal streak line as appearance of test line.
After interpretation time, colloidal gold can appear like line due to drying of test plate with time. Therefore interpret test results at the predetermined time.

2) This product is used as an aid in the diagnosis for infection of mycoplasma. In case that mycoplasma pneumoniae antigen in specimen are below the detection limit of the test or specimen collection is not enough, test result could be interpreted as negative, even though patients are infected by mycoplasma pneumoniae. Moreover, special factors in specimen could cause non-specific reaction and negative specimen could be interpreted as positive. The definitive diagnosis should be made comprehensively in conjunction with the assessment of clinical progress and other test result.

[Performance characteristics]

1) Performance

① Sensitivity
- When in-house positive control note1) was tested, a positive result was shown.

② Accuracy
- When in-house positive control was tested, a positive result was shown.
- When in-house negative control note 2) was tested, a negative result was shown.

③ Reproducibility
- When in-house positive controls were tested three time simultaneously, positive results were shown in all cases.
- When in-house negative controls were tested three time simultaneously, negative results were shown in all cases.

Note 1) Mycoplasma pneumoniae purified antigen is diluted by extraction reagent solution to be equivalent to 1.1 × 10^7 copies/mL of calibration reference material

Note 2) Extraction reagent solution

④ Detection limit
2.8×10^6copies/mL

2) Correlation

Comparison with existing approval product (immmunochromatographic assay)

Quick Chaser® Myco

Other product		Positive	Negative	Total
	Positive	49	5 ※1	54
	Negative	2 ※2	117	119
	Total	51	122	173

Positive agreement rate : 90.7%(49/54)
Negative agreement rate : 98.3%(117/119)
Total agreement rate : 96.0%(166/173)

※1 Regarding 5 specimens with positive by other product , but negative by Quick Chaser Myco, they were negative by Real time PCR.

※2 Regarding 2 specimens with negative by other product, but positive by Quick Chaser Myco, they were positive by Real time PCR.

Comparison with Real time PCR

Quick Chaser® Myco

Real time PCR		Positive	Negative	Total
	Positive	46	10	56
	Negative	0	67	67
	Total	46	77	123

Positive agreement rate : 82.1%(46/56)
Negative agreement rate : 100.0%(67/67)
Total agreement rate : 91.9%(113/123)

3) Calibration reference material (Standard material)
In-house prepared mycoplasma pneumoniae antigen solution (in-house standard)

[Precautions for use and handling]

1) Precautions for handling (Prevention of danger)
   ① Infectious materials such as HIV, HBV and HCV could be included in sample (specimen). Be careful of handling sample (specimen) as potentially infectious materials.
   ② Be careful not to touch sample (specimen) or extraction reagent solution directly to skin or not to get into eyes in wearing glasses, disposable gloves or mask at the time of use.
   ③ Do not use swab to collect specimen, if it is already put into extraction reagent solution.
   ④ If specimen and/or extraction reagent solution are got into eyes or mouth, flush with a plenty of water as emergency treatment and see a doctor if necessary.
   ⑤ Do not use blue cap which belongs to kit for transportation or preservation because it does not have seal strength.
   ⑥ Perform the collection of specimen under the guidance of the qualified person.
   ⑦ Raw material of membrane which is used for test plate, is nitrocellulose. Do not perform test near fire because nitrocellulose is extremely flammable material.
   ⑧ Wipe off with ethanol for disinfectant in case of getting splattered with sample (specimen).

2) Precautions for use
   ① Do not freeze this product. Store this product in accordance with description of instruction for use. Do not use frozen reagents because they could show false result by change of quality.
   ② Do not use this product beyond expiration date.
   ③ Do not store extraction reagent solution vial with falling sideways and an inverting.
   ④ Do not use the extraction reagent solution of other products, using the one included in this kit.
   ⑤ Use the test plate immediately after opening aluminum foil pouch. If test plate is left in a room for a long time, it could not react by exposure to moisture.
   ⑥ Do not touch sample area, test line area and control line area by hands directly.
   ⑦ Do not perform test in the place such as under air conditioner where the dry wind directly blows the surface of the test plate, to prevent uneven migration.
   ⑧ Do not use the reagent and the accessories etc. of this product except the purpose of this testing.
   ⑨ Test plate, swab and extraction reagent solution vial (Filter pink cap and blue cap are included) are intended for single use only.
   ⑩ Use swab included in this kit.
   ⑪ Swab included in this kit is for pharynges. Do not use it by mistake in the place except the pharynxes such as eyes, an ear, and the nasal cavity.
   ⑫ Do not touch spherical tip of swab by hands before use.
   ⑬ Use swab immediately after opening the pouch.
   ⑭ If break and/or hole are found on the pouch of swab, do not use it because swab has been sterilized.
   ⑮ If swab is stained, broken or bent, do not use it.
   ⑯ Do not bend and curve the rod of swab before collecting specimen.
   ⑰ Be careful not to break the rod of swab and injure region to be collected (mucous membrane) by excessive force or pushing too hard at the time of specimen collection.
   ⑱ Be careful not to splatter the sample at the time of taking the swab out of vial after preparing sample.
   ⑲ In case that collection volume of specimen is excessive or the viscosity of the specimen is high, membrane filter could be clogged and the sample of appropriate quantity may not be dropped. Restart from specimen collection using new extraction reagent solution and retest it.

3) Precautions for waste disposal
   ① Treat liquid waste and used utensils by any one of following methods because sample (specimen) could contain other infectious material such as HIV, HBV or HCV.
      a) Immerse in sodium hypochlorite solution (effective chlorine concentration of 1,000 ppm) for 1 hour or more
      b) Immerse in 2 % glutaraldehyde solution for 1 hour or more
      c) Autoclave at 121 degree Celsius for 20 minutes or more
   ② Regarding disposal of used reagent and utensils, dispose of them in accordance with Local Regulation and Law of waste disposal.

[Storage and Expiry]

・Storage : 1～30℃
・Expiry : 24 months (As indicated on package)

Technical information
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